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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/825,992	Applicant(s) TUTUNCU ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 10, 11, 13-21, 23, 24 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-8, 10-11, 13-21, 23-24, and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Amendments/Remarks filed 11/20/06 is acknowledged. Claims 1-5, 7-8, 10-11, 13-21, 23-24, and 28 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-5, 7-8, 10-11, 15-18, 23-24 under 35 U.S.C. 103(a) as being unpatentable over Hanke (6,231,900) is withdrawn in view of applicant's amendments on 11/20/06.

The rejection of claims 20-21 under 35 U.S.C. 103(a) as being unpatentable over Hanke (6,231,900) in further view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999 is withdrawn in view of applicant's amendments on 11/20/06.

The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over US patent 6,231,900 to Hanke in view of US patent 6,099,880 to Klacik et al is withdrawn in view of applicant's amendments on 11/20/06.

Claims 1-5, 7-8, 10-11, 13-14, 17, 20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al.

Cherukuri et al disclose encapsulated flavor with bioadhesive properties. The compressed confectionary provides controlled release of the flavor and a unique mouthfeel by using bioadhesives. The compressed tablet is characterized by discrete phases contained within. See Figure 5 and 6 wherein both phase 1 and 2 have a surface on the exterior of the product.

The compressed tablet include: (a) a first flavor ingredient present in an amount from about 0.1% to 0.5% by weight of a hydrophilic composition with which it is intimately bound to provide instantaneous delivery of the active ingredient; and (b) a second flavor ingredient present in an amount of from about 3% to 30% by weight of a hydrophobic encapsulating composition containing a bioadhesive so as to provide delivery of the second flavor ingredient over a period of time while both the tablet and encapsulated flavors adhere to the moist areas of the oral cavity.

The confectionary compressed tablet is made of a sugar or sugarless base. See column 8, lines 66-67 and column 10, lines 40-45. Sugars taught include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. See column 9, lines 7-21. Emulsifiers (surfactants) are taught in an amount of 2-7%. See column 8, lines 40-55.

Cherukuri also teaches that in addition to encapsulated flavor ingredients, a bio-effecting agent such as breath fresheners, breath deodorants, *antigingivitis agents*, and combinations thereof may also be used. See column 7, lines 30-45.

Table II, example III discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor. This shell region reads on instant “salivation region” since this region contains the bio-effecting agent (the breath freshener). The core comprises 40.32% fat encapsulation material of Table I and 59.68% of a diluent. Table I discloses a fat encapsulation containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. This core region read on instant “oral comfort region” since this phase predominantly comprises lipids. Cherukuri teaches the diluent may be selected from lactose (sugar), microcrystalline cellulose, starch, talc, sorbitol, mannitol, xylitol, maltitol, xylitol, other sugar alcohols or sugars. See column 8, lines 60-65. Note that this diluent reads on applicant’s confectionary base of the oral comfort region. The tablet is made by mixing each respective composition with the respective components separately and then the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Although Cherukuri teaches the use of bioeffecting agents in the shell portion, Cherukuri does not teach the specific use of an acidulent in the shell portion.

Le teaches co-processed comestible, confectioneries, pharmaceuticals, and dentifrices comprising an acid and water-soluble crystalline compounds. Le teaches that the prior art conventionally uses acidulents in comestible for a variety of reasons. For instance, acidulents may be used to increase saliva production for the treatment of xerostomia and dry mouth; the use

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of acids to soften plaque on teeth; as flavor enhancers to improve the release of flavor in confectionary products such as hard candies. See page 1. Le teaches the acidulent may be inorganic or organic acids including phosphoric acid, citric acid, malic acid, succinic acid, fumaric acid, ascorbic acid, etc. see page 5, lines 13-25. The acidulent is utilized in an amount of 0.2% of the entire composition (note example 4 in combination with Table 2 formulation wherein the acidulent is 5.5% of the coprocessed formulation and the coprocessed formulation is 3.75% of the composition)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Cherukuri et al and Le et al and utilize an acidulent as the bio-effecting agent in the shell portion of Cherukuri's composition. Firstly, one would have been motivated to do so with a reasonable expectation of success since Cherukuri teaches the use of bio-effecting composition in the composition; thus a skilled artisan would have been motivated to utilize an acidulent in Cherukuri's example as the bio-effecting agent in place of the breath freshener if one desired to treat xerostomia and dry mouth or reduce plaque on the teeth. A skilled artisan would have reasonably expected success since Cherukuri teaches various bio-effecting agents may be used including antigingivitis agents and Le teaches the acids reduce plaque, i.e. having an antigingivitis activity. Secondly, one would have been motivated to utilize an acidulent in the shell portion since Cherukuri teaches the shell portion provides the release of the first flavor (the rapid release portion) and thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. Therefore, a skilled artisan would have been

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motivated to utilize an acidulent in the shell portion to increase the rate of release of first flavor in the hydrophilic portion (shell portion).

With regard to claim 14, the manipulation of the concentration of emulsifier in the core composition of example III is considered to be obvious to one of ordinary skill. The examples utilize a range of 5%, however one would have been motivated to utilize the instant range of 0.5-4% since Cherukuri teaches the emulsifier may be utilized in a range of 2-7%. Therefore, the range taught by Cherukuri overlaps the instant range.

Response to Arguments

Applicant argues that the Office Action maintains that the region comprising the bio-effecting reads on the salivating region but Cherukuri does not teach the use of an acidulent. Applicant argues that one would not consider the description of the diluent to read on a sugar or sugarless confectionary base. Applicant argues that the Office Action never indicates that once the proposed modification is made there would be a region that promotes salivation and another region that provides oral comfort. Applicant argues that the motivation is insufficient because “one is required to have the desire to achieve the desired result, the treatment of xerostomia, before setting out on the modification of the references, which is hindsight.” Applicant argues that that second motivation is also hindsight.

Applicant's arguments filed 11/20/06 have been fully considered but they are not persuasive. As stated in the rejection, the examiner interprets Cherukuri's shell portion to read on the instant salivation region since it comprises the bio-effecting agent and the core portion reads on the “oral comfort region” since it predominately contains lipids. The examiner notes that Cherukuri does not teach an acidulent and hence the rejection is made under obviousness and in

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view of WO 99/579427. The examiner points out that the combination of Cherukuri and Le provides for a confectionary product comprising a salivation region containing an acid and an oral comfort region containing a lipid. Firstly, the motivation to utilize bio-effecting agents comes from the primary reference itself. Cherukuri teaches the use of bio-effecting agents such as breath fresheners, breath deodorants, *antigingivitis agents*. Le provides the motivation to utilize acidulents specifically. Le teaches acidulents are known in the art to treat xerostomia, reduce plaque on teeth (this provide an antigingivitis property since reduction of plaque reduces the likelihood of gingivitis from occurring), and to enhance, and improve flavor release. Therefore, a skilled artisan would have been motivated to utilize acidulents specifically as the bio-effecting agent for the advantages taught by Le. Moreover, Cherukuri teaches the shell portion is the rapid release portion and provides the release of the first flavor; thus a skilled artisan would have been motivated to utilize an acidulent in the shell portion since Le teaches acidulents are conventionally utilized to improve and enhance the release of the flavor. Applicant has not provided any unexpected results to overcome this rejection.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case, the examiner points out that the secondary reference teaches the routine and conventional use of acidulents in confectionary products for

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various reasons including treating xerostomia, improving and enhancing flavor release, and reducing plaque on the teeth. Therefore, the “desired result” has not been gleaned by applicant’s disclosure and rather is conventional knowledge in the art as taught by Le.

With regard to applicant’s argument that Cherukuri does not teach a sugar or sugarless base, the examiner points out that example 1 teaches the shell base comprises 97.676% sugar. Cherukuri further teaches on column 8, lines 66-68, “the present invention includes both sugar-containing and sugarless confectionary compressed tablets.” On column 9, lines 9-21, Cherukuri teaches sugars include sucrose, glucose, dextrose, fructose, and sugar alcohols include sorbitol, mannitol, and xylitol. As acknowledged by applicant, the core comprises 40.12% or 59.68% of a diluent wherein the diluent may be lactose (sugar), microcrystalline cellulose, starch, sorbitol (sugar alcohol), Palatinit (sugar free excipient), mannitol (sugar alcohol), maltitol (sugar alcohol), xylitol (sugar alcohol), “other sugar alcohol”, and sugar. Thus, Clearly Cherukuri suggests the use of a sugar alcohols or sugars as the diluent. Therefore, there is a suggestion for both regions comprise a sugar or sugarless base. Further, it should be noted that the phrase “sugarless base” is broadly interpreted to mean a base that does not have sugar. Thus, if cellulose or starch is utilized as the diluent, then it would read on sugarless base.

With regard to applicant’s argument that the proposed modification does not teach a region to promote salivation and a region to provide oral comfort, the examiner points out that the combination provides for separate regions comprising the required components. It is pointed out that the examiner’s motivation does not need to be the same as applicant’s. The fact that applicant has a different reason to combine the references does not provide a patentable distinction. The fact that applicant has recognized another advantage which would flow naturally

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from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The applicant has not provided any unexpected results or persuasive arguments to overcome the rejection based on obviousness.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/59427 to Le et al in further view of Aldrich (4,517,205).

The disclosure of Cherukuri and Le have been set forth above.

The reference do not teach the instant method of making the confectionary product.

Aldrich teaches a method of co-depositing two component hard candy in a mold cavity that produces two distinct areas. See column 2, lines 15-30 and Figures. The method provides an efficient method that is readily adaptable to commercial production of candies with two components. See column 2, lines 5-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and simultaneously deposit the two distinct regions in a mold cavity. One would have been motivated to do so since Aldrich teaches this it is an efficient method that is easily adaptable for commercial production of candies comprising two-components such as a shell portion and core portion.

Claims 15-16, 21, 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,284,659 to Cherukuri et al in view of WO 99/579427 to Le et al in further view of Hughes (6,004,538).

The disclosure of Cherukuri and Le have been set forth above.

The combination of references is lacking the use of an acidulent and the cooling compound specifically.

Hughes teaches an oral composition in various forms including candies. Hughes teaches dental hygiene preparations typically contain antiplaque and/or antitartar agents, as well as antimicrobial agents and flavorants. Hughes teaches antimicrobial action could affect plaque formation by either reducing the number of bacteria in the mouth/dentures or by killing those bacteria trapped in the film to prevent further growth and metabolism. Flavorants may alleviate the problem of bad breath via a deodorizing action. Hughes teaches some antimicrobial agents, such as menthol, also serve as breath deodorizers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and utilize menthol as the flavorant taught in Cherukuri's shell. One would have been motivated to do so since Hughes teaches menthol not only serves as a flavorant but it reduces plaque on the teeth due to its antimicrobial action and it reduces bad breath. Therefore, a skilled artisan would have been motivated to specifically utilize menthol as the flavorant in the shell portion for its various advantageous functions. Moreover, one would have specifically utilizes menthol in the shell area specifically since the shell area comprises the bioeffecting agents. Further, Le teaches the use of acids not soften plaque on the teeth and thus a skilled artisan would have been motivated to additionally utilize menthol for its additive effect.

Claims 1-5, 7-8, 13-18, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695.

Bealin-Kelly teaches a confectionary composition comprising cooling and warming regions, which are in distinct and discrete regions. Bealin-Kelly teaches that various configurations may be utilized including a centre-filled drop that provides a sequential release of the compositions or a configuration that provides differential release profiles as described in WO97/06695, which is incorporated by reference. See column 2, lines 10-25.

Bealin-Kelly teaches sugar base for a hard candy shell comprises from about 30% to about 85% glucose syrup and from about 15% to about 70% sucrose. Alternatively, a sugar-free base maybe used for the shell including bulk sweeteners such as isomalt, maltitol and sorbitol. Isomalt and maltitol are preferred. See column 6, lines 1-15. The "filling" is made of 50-75% of bulk sweetener and may be made of sugar free composition such as sorbitols. See column 5, lines 40-45. Phospholipids such as lecithin are used in an amount of 0.001-1%. See column 5, lines 20-25.

Example 1 teaches a composition comprising a candy containing 49.37% sucrose, 49.37% glucose syrup, 0.27% lemon oil, 0.08% menthol (cooling compound), and 0.91% citric acid (acidulent). The filing contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin (surfactant), 0.314% lemon oil, and 0.16% color. See example 1. Note that the shell reads on the instant salivation region and the fill reads on the oral comfort region. The regions are mixed separately and co-extruded.

Bealin-Kelly does not exemplify the instant configuration.

WO '695 teaches a confectionary product comprising a coolant composition and flavoring composition in separate and distinct regions. The composition may take various form including hard candies wherein the distinct regions are in separate layers. See page 3. WO '695

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teaches using molds in which the respective composition is placed and each composition has a surface on the exterior of the product. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made Bealin-Kelly and WO '695 and utilize a configuration wherein the respective compositions are in separate layers rather than a "centre-filled drop". One would have been motivated to do so with a reasonable expectation of success since Bealin-Kelly incorporates the teachings of WO '695 and suggests various configurations may be used including the configuration taught in WO '695, i.e. distinct regions.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695 in further view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999.

The disclosure of Bealin-Kelly and WO '695 have been set forth above.

Although Bealin-Kelly teaches the use of the confectionary product for providing soothing properties, Bealin-Kelly does not specifically teach the use of the product to treat xerostomia.

The NIH publication teaches xerostomia (dry mouth) is caused by several factors such as the side effects of medication, diseases, chemotherapy, etc. The symptoms include sticky, dry mouth, trouble chewing, swallowing, tasting, a burning feeling in the mouth, a dry feeling in the throat, cracked lips, a dry tongue, and mouth sores. The publication teaches methods of treating xerostomia include, chewing sugarless gum or sucking on sugarless gum to stimulate saliva flow. Candies that have citrus, cinnamon, or mint are good choices.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and Bealin-Kelly's composition to treat xerostomia. One would have been motivated to do so since Bealin-Kelly teaches a sugarless confectionary product containing citrus flavors and menthol and the NIH publication teaches sucking on sugarless candies, particularly ones that contains citrus and mint, treat xerostomia. Furthermore, a skilled artisan would have expected success since Bealin-Kelly teaches the confectionary provide soothing properties and the symptoms of dry mouth include a burning feeling in the mouth and dry feeling in the mouth, and mouth sores.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429) in view of WO 97/06695 in further view of US patent 6,099,880 to Klacik et al.

The disclosure of Bealin-Kelly and WO '695 have been set forth above.

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method is a simple method of forming distinct regions. See column 1, lines 30-50.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

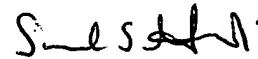
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila S. Gollamudi
Examiner
Art Unit 1616